

MEDICAL DEVICES INDUSTRY IN IRAN

NOVEMBER 2020

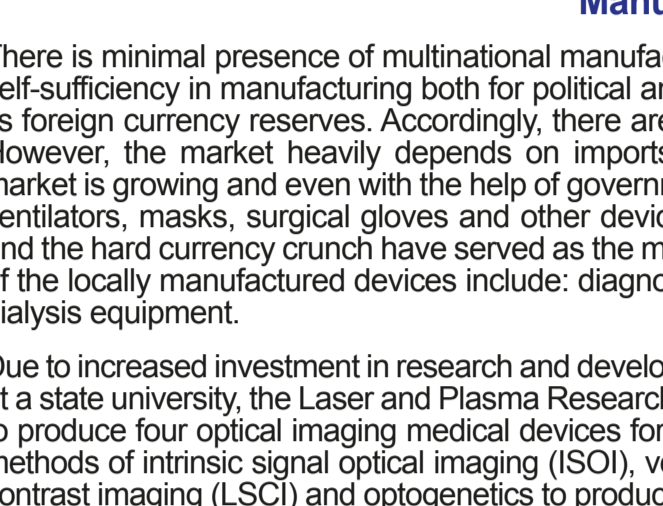
TABLE OF CONTENTS

- INTRODUCTION
- MARKET SIZE
- MANUFACTURING
- DOMESTIC MARKET PLAYERS
- EUROPEAN MARKET PLAYERS
- REGULATORY STRUCTURE
- CLASSIFICATION OF MEDICAL DEVICES
- NEW DEVELOPMENTS IN TRADE IN MEDICAL DEVICES BETWEEN EUROPE & IRAN
- OPPORTUNITIES
- CHALLENGES
- TRADE OPPORTUNITIES IN THE IRANIAN MEDICAL DEVICES INDUSTRY
- IMPORTS
- EXPORTS
- IMPORTANCE OF PAYMENT VEHICLES (INSTEX)
- OUTLOOK
- IMPACT OF COVID-19 ON THE IRANIAN MEDICAL DEVICES INDUSTRY
- IDENTIFYING GROWTH SEGMENTS FOR EUROPEAN SMEs



EUROPEAN PRESENCE

Most of the major international medical devices providers including European players are present in Iran. Their presence is mostly indirect with more than 100 Iranian companies representing the international suppliers. These representatives handle both promotion and after sales service on behalf of the international manufacturers. Iran is a mature market when it comes to medical equipment warranting competition among major global brands in this sector. Some of the European medical device manufacturers present in Iran include: Medtronic, Philips, Siemens, and Smith & Nephew.



INTRODUCTION

Iran possesses the fifth largest medical device market in the region. Although the local government is highly committed to self-sufficiency, compliance of its production sites with international standards and an increase in production, the industry is highly import driven. The market consists of 88% imports with more than 70.4% of these imports coming from Europe, namely Germany and the Netherlands. Continued growth is expected in the medical devices sector to address the shortage of specialised devices. Currently, this market stands at €1 billion.

Iran has strived to improve this sector with a focus on enhancing the quality of care it offers its citizens and the pent up demand for quality medical, dental and surgical services that require the use of sophisticated diagnostic and treatment devices and equipment. Medical tourism has been instrumental in increasing demand for medical equipment and devices, especially those used in ophthalmology, surgical procedures (cosmetic, dermatopaedics, cardiac and thoracic) as well as dermatology. Medical tourism has been flourishing in Iran as it offers quality expertise at lower costs. In 2019, there were more than 600,000 people traveling to Iran for medical services who came from neighbouring countries including: Azerbaijan, Turkmenistan, Iraq, Turkey, Kuwait, Oman, India, Pakistan, and UAE.

This figure does not include the number of Iranians living abroad that travel to Iran from Europe and the USA for cosmetic surgeries. Iran is heavily investing in the medical industry by increasing the number of high-end medical facilities as well as providing incentives to the private sector to offer better medical services to both its citizens and the medical tourists to become the medical regional hub in the future.

MARKET SIZE

The demand for medical services relies on innovative and sophisticated diagnostic medical devices and equipment. Although Iran strives towards self-sufficiency in the medical devices industry, out of more than 500,000 types of medical devices manufactured globally, there are only 280,000 that are available in Iran. 33,000 types of medical devices available in Iran are "in vitro diagnostic devices (IVD)", of which 89% are imported.

Manufacturing

There is minimal presence of multinational manufacturing sites locally. Iran tends to lean towards promoting self-sufficiency in manufacturing both for political and economic reasons in an effort to improve the status of its foreign currency reserves. Accordingly, there are in excess of 500 medical device manufacturers in Iran. However, the market heavily depends on imports for more sophisticated devices and instruments. The market is growing and even with the help of government funding, some startups have helped to manufacture ventilators, masks, surgical gloves and other devices during the current pandemic. International sanctions and the hard currency crunch have served as the main impetus for the growth of these manufacturers. Some of the locally manufactured devices include: diagnostic medical imaging equipment, oxygen generators and dialysis equipment.

Due to increased investment in research and development (R&D) by the government, a major research centre at a state university, the Laser and Plasma Research Institute (LAPRI) of Shahid Beheshti University was able to produce four optical imaging medical devices for brain and optogenetic examinations. These devices use methods of intrinsic signal optical imaging (ISOI), voltage sensitive dyes (potentiometric dyes), laser speckle contrast imaging (LSCI) and optogenetics to produce images from the human brain.

DOMESTIC MARKET PLAYERS

Iran provides different types of incentives and grants for this sector and the private sector is most active in both manufacturing and import of medical devices. Some major players include: *Bandhayeh Pezeshki*, a producer of disposables including different types of gauze and bandages; *Behzisty Cooperative*, a manufacturer of various types of hospital equipment including products related to rehabilitation, physiotherapy, audio metrics and speech therapy; *East Advanced Medical*, with a speciality in manufacturing dual trace ECG monitors; and *Farafan*, a manufacturer of a full range of medical devices including cardiac monitors, operating and physiotherapy tables, specialised hospital beds, pulse oximeters, spacers, spirometers and syringe pumps. Others include *Helal Iran Medical Devices Company (Soha)* who as part of the Iranian Red Crescent Organization manufactures disposable medical devices in Iran including syringes and dialysis products; and *Supa Medical Devices* who is the largest manufacturer of sterile, single use medical devices in Iran. *Libtron*, *Pooya Tab* and *Paya Pajooheh Pars* manufacture laboratory equipment and devices including tissue processors, blood centrifuge units and electrophoresis systems while others rely on European partners like Medite (pathology devices) and Kern (precision scales) both from Germany.

REGULATORY STRUCTURE

The Iranian Food and Drug Administration Agency (IFDA) is the main regulator for the manufacture and import of any medical device into Iran. The Department of Medical Equipment at the Ministry of Health and Medical Education (MOHME) is responsible for supervising imports. The major import and distribution of medical devices is usually handled by the private sector. According to the IFDA, all equipment and medical supplies including any product, devices, equipment, tools and accessories, machinery, implant, material, reactive, laboratory calibrator, software, intended by the manufacturer to be used (alone or in combination with other items) for humans for the following purposes is considered a medical device:

1. Diagnosis, monitoring, prevention, or treatment of disease reduction;
2. Continue life support or support;
3. Control and contraception;
4. Creation of a process sterilisation or disinfection and cleaning equipment, environment and medical wastes to desirable carrying out medical, therapeutic and health;
5. Provision of information for medical purposes by laboratory methods on human samples;
6. Diagnosis, monitoring, treatment, relief, compensation or correction of injury or disability replacement or modification of physiological or anatomical processes;
7. Study, evaluation and replacement or correction of physiology or anatomic process; or
8. Regulations of equipment and medical supplies.

EUROPEAN MARKET PLAYERS

The leading multinational companies do not have a strong direct presence in Iran; none of the leading companies have any local offices and all products are imported via local agents or distributors including Philips. It provides diagnostic imaging, ultrasound, healthcare informatics and image-guided therapy equipment and devices. Philips also offers monitoring & analytics, therapeutic care, population health management and sleep & respiratory care solutions. It also provides Iran with medical devices used in conjunction with personal health.

Fig. 1- Classification of Medical Devices

International Classification (GHTF)	Examples	Risk Level
Class A	Simple surgical instruments, tongue depressor	Low
Class B	Digestive catheters, infusion pumps, and powered wheelchairs	Low-Moderate
Class C	Dialysers, and orthopaedic implants	High-Moderate
Class D	Coronary stents	High

Fig. 2- Pre-market Approval Process



All standard medical devices qualify for the general licence unless they appear on the exclusion list issued by the Medical Device Board (MDB).

The MDB will review the application and approve the product if it qualifies. The review process considers the safety and performance of the medical equipment and supplies. The registration licence is valid for four years and batch release for high-risk medical equipment is necessary. Import of any used or refurbished medical equipment is prohibited in Iran unless there is a special permission granted by the MDB.

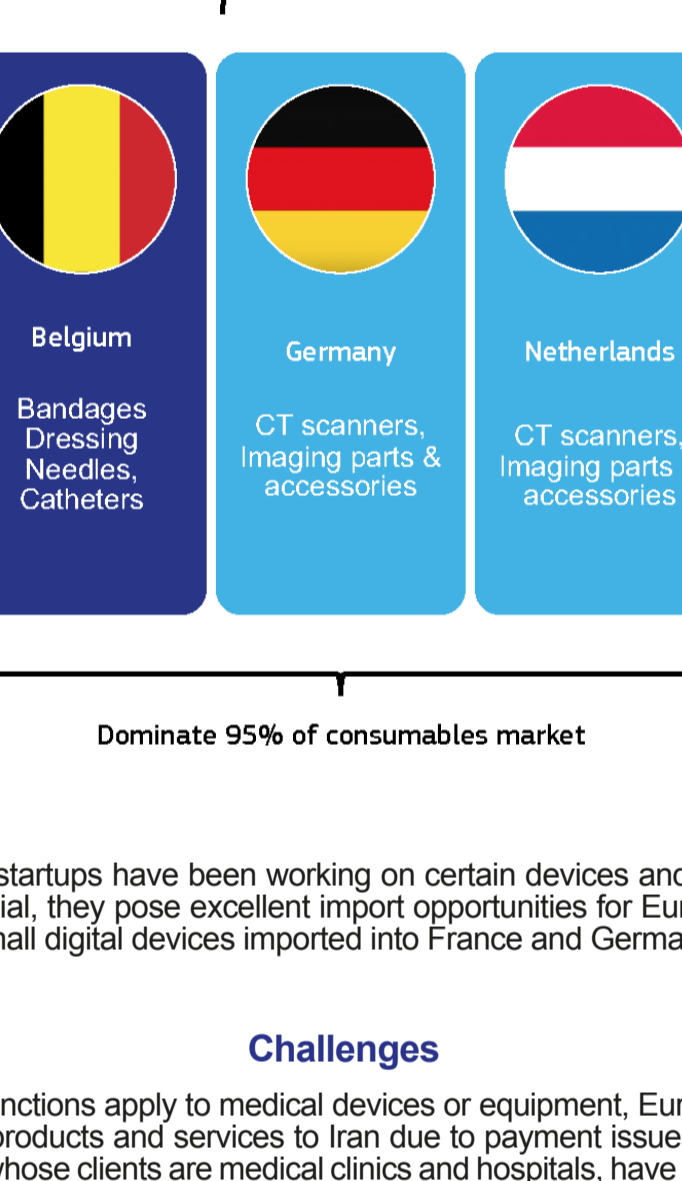
NEW DEVELOPMENTS IN TRADE IN MEDICAL DEVICES BETWEEN EUROPE & IRAN

Opportunities

Given the significant progress in the medical sector due to government funding and incentives available in this sector, European companies are poised to benefit from this market. The population welcomes and trusts Iranian medical devices. Iranians trust the European products more than local products or other imports.

What makes the market attractive is the population dynamics with the baby boomer generation of the 1980s requiring medical care as well as high demand for all types of imaging and diagnostic devices. In addition, the medical device market's size is large by regional standards.

European companies dominate in all market segments with 95% of supplies in consumables (bandages, dressings, suturing materials, syringes, needles & catheters) imported from Belgium, Germany, and the Netherlands. Imports from the Netherlands and Germany dominate the diagnostic imaging market. In the electro-diagnostic apparatus market, viewed as the most dynamic market segment, the EU is the leading supplier accounting for in excess of 55% of imports comprising 90% of the market segment. The demand will be high for radiation therapy including CT scanners with the EU dominating 75% of this market segment, led by the Netherlands and Germany. Imports dominate in other subcategories like imaging parts and accessories with 95% of the supplies being imported with the EU as the leading supplier, accounting for 70% of the imports.



On the other hand, Iranian startups have been working on opportunities and equipment that because of devaluation of the Iranian Rial, they pose excellent import opportunities for European companies. Case in point is wheel chairs and small digital devices imported into France and Germany from Iran.

Challenges

Although no international sanctions apply to medical devices or equipment, European exporters have faced challenges in offering their products and services to Iran due to payment issues. Despite these challenges, larger European operators whose clients are medical clinics and hospitals, have resolved the payment issues by offering flexible terms and using alternative modes of payment. Other challenges include strict foreign exchange and import regulations albeit somehow relaxed due to the pandemic. European exporters with similar products manufactured locally face high taxes and customs tariffs; whereas, those without a locally produced equivalent enjoy low taxes and customs tariffs. Therefore, prior to considering exports to Iran, a European firm should conduct market research to ensure that similar products are not available locally.

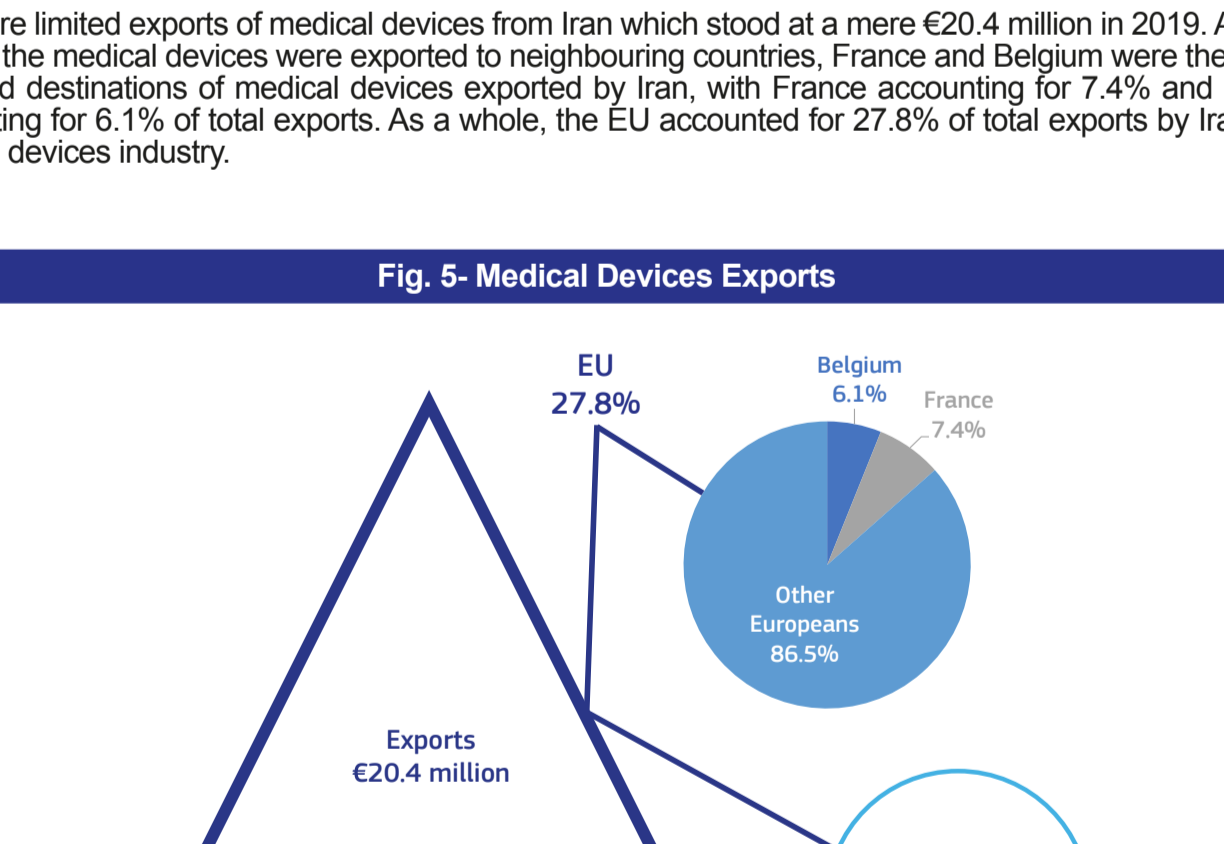
TRADE OPPORTUNITIES IN THE IRANIAN MEDICAL DEVICES INDUSTRY

IMPORTS

Diagnostic imaging and consumables comprise the largest market segments accounting for around 47% of total imports, followed by other medical devices, patient aids, orthopaedics & prosthetics and dental products. Consumables are the second fastest growing product area after dental products. In 2018, the leading supplier was the Netherlands, providing €180.4 million, equal to 22.2% of the total imports in this industry. Major imports from the Netherlands were diagnostic imaging, dental and other medical devices (wheelchairs).

In 2018, the EU supplied 61% of all imports in medical devices, of which most came from the Netherlands and Germany (10.6%). Other leading EU suppliers included Belgium (7.2%) and France (6.5%).

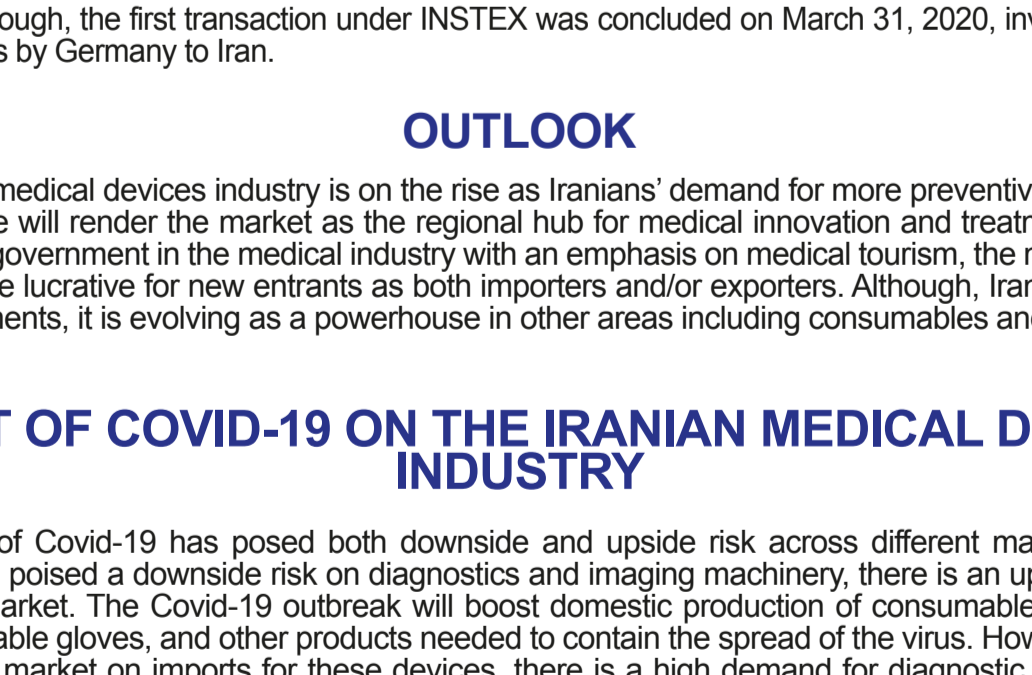
Fig. 4- Medical Devices Imports



EXPORTS

There are limited exports of medical devices from Iran which stood at a mere €20.4 million in 2019. Although most of the medical devices were exported to neighbouring countries, France and Belgium were the second and third destinations of medical devices exported by Iran, with France accounting for 7.4% and Belgium accounting for 6.1% of total exports. As a whole, the EU accounted for 27.8% of total exports by Iran in the medical devices industry.

Fig. 5- Medical Devices Exports



IMPORTANCE OF PAYMENT VEHICLES (INSTEX)

INSTEX (Instrument in support of trade exchanges) is a special purpose vehicle designed to facilitate "legitimate" Iran-related trade by European businesses. It applies a netting system to import and export payments in coordination with Iran's Special Trade and Finance Institute ("STFI"). INSTEX was set up to offer European businesses an alternative platform to the traditional financial system so that they can perform legitimate trading with Iran in support of the JCPOA.

Interestingly enough, the first transaction under INSTEX was concluded on March 31, 2020, involving a sale of medical devices by Germany to Iran.

OUTLOOK

The domestic medical devices industry is on the rise as Iranians' demand for more preventive medicine and digital medicine will render the market as the regional hub for medical innovation and treatment. Given the interest of the government in the medical industry with an emphasis on medical tourism, the medical devices industry may be lucrative for new entrants as both importers and/or exporters. Although, Iran is not a player in certain segments, it is evolving as a powerhouse in other areas including consumables and small devices.

IMPACT OF COVID-19 ON THE IRANIAN MEDICAL DEVICES INDUSTRY

The outbreak of Covid-19 has posed both downside and upside risk across different market segments. Although it has posed a downside risk on diagnostics and imaging machinery, there is an upside risk to the consumable market. The Covid-19 outbreak will boost domestic production of consumables such as face masks, disposable gloves, and other products needed to contain the spread of the virus. However, given the reliance of the market on imports for these devices, there is a high demand for diagnostic equipment and devices used in connection with the pandemic. Although some consumables are produced locally including simple face masks and disposable gloves, there is a high demand for European exports of other devices including no-touch thermometers.

Fig. 6- Covid-19 & Medical Device Market in Iran



IDENTIFYING GROWTH SEGMENTS FOR EUROPEAN SMEs

- Surgical, medical & laboratory sterilisers
- Surgical equipment & thread (sutures, Catheters, cannulae, and needles)
- Ophthalmic instruments
- Veterinary appliances & instruments,
- Electrocardiographs
- Ultrasonic diagnostic equipment
- Scintillation scanners
- Nuclear magnetic resonance equipment
- Electro-diagnostic equipment
- Orthopaedics & Prosthetics
- Digital Health Tools & Kits
- Remote sensors & wearables
- Data analytics & intelligence, predictive modelling tools
- Health & wellness behaviour modification tools
- Bioinformatics tools
- 3D Printing Medical Devices (3DP, EBM, LBM, Photo-polymerisation and DD)
- 3D Printers Components
- 3D Bio-printers
- Software & Services
- Organ Implants Technology & associated 3D Printing
- Ostomy Products
- Blood Grouping Reagents

«Wherever the art of Medicine is loved, there is also a love of Humanity»
Hippocrates

For further information, please contact us at:

✉ info@sanctions-helpdesk.eu
🌐 www.sanctions-helpdesk.eu

